State of South Dakota

SEVENTY-NINTH SESSION
LEGISLATIVE ASSEMBLY, 2004

931J0615

HOUSE BILL NO. 1165

Introduced by: Representatives Glenski, Engels, Hunhoff, Kraus, McCoy, Schafer, Smidt, Solum, and Van Gerpen and Senators Dempster and Kleven

FOR AN ACT ENTITLED, An Act to allow certain facilities and hospice programs to redispense certain pharmaceutical drugs under certain circumstances.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. Terms used in this Act mean:

(1) "Assisted living center," as defined in § 34-12-1.1;

(2) "Hospice program," a coordinated program of inpatient services providing palliative rather than curative care for the patient;

(3) "Nursing facility," as defined in § 34-12-1.1;

(4) "Unit dose," a single dose of a drug in an individually sealed, labeled container ready for administration to a particular patient by the prescribed route at the prescribed time.

Section 2. Unused unit dose drugs from patients in a nursing facility, an assisted living center, or a hospice program may be returned to the pharmacy that dispensed the drugs for credit and redispensing if the following requirements are met:

(1) The facility consults with a licensed pharmacist to oversee the drug distribution to

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ensure that a person trained and knowledgeable in the storage, use, and administration of the drug has been in control of any unit dose drug being returned to the pharmacy and that the unit dose drug has not come into the physical possession of the person for whom it was prescribed;

(2) The pharmacy's manager has received written approval from the board of a protocol detailing the procedure used to repackage, label, transfer, restock, redispense, and credit any unit dose drugs returned to the pharmacy;

(3) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the pharmacy in a hermetically sealed single-unit dose container that meets Class A or Class B standards of the United States Pharmacopeia, as of January 1, 2004;

(4) The unit dose package is labeled by the manufacturer with the drug lot number and expiration date;

(5) If the drug is repackaged by the pharmacy, each single-unit dose prepackaged or repackaged container shall have a label that includes the following:

(a) Name and strength of the medication;

(b) A suitable expiration date which may not be later than the expiration date on the manufacturer's container, or one year maximum from the date the drug is prepackaged or repackaged;

(c) The date the product was prepackaged or repackaged;

(d) The manufacturer's lot number, expiration date, and identity;

(e) The identity of the pharmacist responsible for prepackaging or repackaging;

(6) The drug's packaging is tamper resistant and shows no evidence of contamination, such as an opened or stained container;

(7) The unit dose drugs have not reached the expiration date;

(8) The drugs have not been dispensed in packaging that intermingles different drugs in a single compartment; and

(9) The drugs are not controlled drugs.

If the requirements of subsections (d) and (e) of subdivision (5) are maintained in the internal records of the drug outlet, those requirements may be omitted from the labeling.

Section 3. Unused unit dose drugs that are returned pursuant to section 2 of this Act may be redispensed under the following conditions:

(1) Drugs may not be removed and repackaged from the returned unit dose package prior to redispensing;

(2) Drugs in a manufacturer's unit dose package may be redispensed as often as necessary, if the integrity of the original product and package is maintained;

(3) Drugs which have been repackaged into a unit dose package by the pharmacy may be redispensed into a unit dose distribution system and mixed with drugs of a different lot number provided that all lot numbers and expiration dates are placed on the unit dose package;

(4) Drugs may be removed from a unit dose package for dispensing in a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.

Section 4. That ARSD 20:51:13:02.01 be repealed.

~~20:51:13:02.01. Return of unused unit dose drugs by patients in nursing facilities or assisted living facilities. Only unused unit dose drugs from patients in a nursing facility or assisted living facility may be returned to the pharmacy that dispensed the drugs for credit and redispensing if the following requirements are met:~~

~~(1) The facility consults with a licensed pharmacist to oversee the drug distribution to~~

~~ensure that a person trained and knowledgeable in the storage, use, and administration of the drug has been in control of any unit dose drug being returned to the pharmacy and that the unit dose drug has not come into the physical possession of the person for whom it was prescribed;~~

~~(2) The pharmacy's manager has received written approval from the board of a protocol detailing the procedure used to repackage, label, transfer, restock, redispense, and credit any unit dose drugs returned to the pharmacy;~~

~~(3) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the pharmacy in a hermetically sealed single unit dose container that meets Class A or Class B standards on pages 1937 and 1938 of the United States Pharmacopeia;~~

~~(4) The unit dose package is labeled by the manufacturer with the drug lot number and expiration date;~~

~~(5) If the drug is repackaged by the pharmacy, each single unit dose prepackaged or repackaged container must be labeled in accordance with this regulation. Labeling must include the following:~~

~~(a) Name and strength of the medication;~~

~~(b) A suitable expiration date which shall not be later than the expiration date on the manufacturer's container, or one year maximum from the date the drug is prepackaged or repackaged;~~

~~(c) The date the product was prepackaged or repackaged;~~

~~(d) The manufacturer's lot number, expiration date, and identity;~~

~~(e) The identity of the pharmacist responsible for prepackaging or repackaging;~~

~~If the requirements of subdivisions (d) and (e) are maintained in the internal records of the drug outlet, those requirements may be omitted from the labeling.~~

~~(6) The drug's packaging is tamper resistant and shows no evidence of contamination, such~~

~~as an opened or stained container;~~

~~(7) The unit dose drugs have not reached the expiration date;~~

~~(8) The drugs have not been dispensed in packaging that intermingles different drugs in a single compartment; and~~

~~(9) The drugs are not controlled drugs.~~

~~Unused unit dose drugs that are returned under this section may be redispensed pursuant to § 20:51:13:02.03.~~

Section 5. That ARSD 20:51:13:02.03 be repealed.

~~20:51:13:02.03. Redispensing unit dose drugs returned from nursing facilities or assisted living facilities. Unused unit dose drugs that are returned under § 20:51:13:02.01 may be redispensed under the following conditions:~~

~~(1) Drugs may not be removed and repackaged from the returned unit dose package prior to redispensing;~~

~~(2) Drugs in a manufacturer's unit dose package may be redispensed as often as necessary, if the integrity of the original product and package is maintained;~~

~~(3) Drugs which have been repackaged into a unit dose package by the pharmacy may be redispensed into a unit dose distribution system and mixed with drugs of a different lot number provided that all lot numbers and expiration dates are placed on the unit dose package;~~

~~(4) Drugs may be removed from a unit dose package for dispensing in a traditional dispensing system as defined in § 20:51:21:01.~~